

of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on [regulations.gov](http://regulations.gov) may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010-30991 Filed 12-8-10; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-E-0021]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; SABRIL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for SABRIL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was

marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SABRIL (vigabatrin). SABRIL is indicated for refractory complex partial seizures in adults. It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SABRIL (U.S. Patent No. 5,380,936) from Lundbeck, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SABRIL represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SABRIL is 10,205 days. Of this time, 4,614 days occurred during the testing phase of the regulatory review period, while 5,591 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FFD&C act) (21 U.S.C. 355(i)) became effective:* September 14, 1981. FDA has verified the applicant's claim that the date the

investigational new drug application became effective was on September 14, 1981.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FFD&C act:* May 2, 1994. The applicant claims April 29, 1994, as the date the first new drug application (NDA) for SABRIL (NDA 20-427) was initially submitted. However, FDA records indicate that NDA 20-427 was submitted on May 2, 1994.

3. *The date the application was approved:* August 21, 2009. FDA has verified the applicant's claims that NDA 20-427 (vigabatrin tablets) and NDA 22-006 (vigabatrin powder for oral solution) were approved on August 21, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments and ask for a redetermination by February 7, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 7, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on [regulations.gov](http://regulations.gov) may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

Jane A. Axelrad,  
Associate Director for Policy, Center for Drug  
Evaluation and Research.

[FR Doc. 2010-30995 Filed 12-8-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Mental Health Council.

*Date:* January 13-14, 2011.

*Closed:* January 13, 2011, 11 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

*Open:* January 14, 2011, 8:30 a.m. to 12:30 p.m.

*Agenda:* Presentation of NIMH Director's report and discussion on NIMH program and policy issues.

*Place:* National Institutes of Health, Building 31, C Wing, 31 Center Drive, 6th Floor, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Jane A. Steinberg, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892-9609, 301-443-5047.

Any member of the public interested in presenting oral comments to the

committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: December 3, 2010.

Jennifer S. Spaeth,  
Director, Office of Federal Advisory  
Committee Policy.

[FR Doc. 2010-30963 Filed 12-8-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: NIH Exploratory Developmental Research Grant Program In Urology.

*Date:* December 22, 2010.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Mushtaq A. Khan, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301-435-1778, [khanm@csr.nih.gov](mailto:khanm@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 3, 2010.

Jennifer S. Spaeth,  
Director, Office of Federal Advisory  
Committee Policy.

[FR Doc. 2010-30961 Filed 12-8-10; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2010-1085]

#### Detecting Oil Leaks From Vessels Into the Water

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for information.

**SUMMARY:** In section 707 of the Coast Guard Authorization Act of 2010, Congress directs the Secretary of the Department in which the Coast Guard is operating to report on the availability, feasibility, and potential cost of technology to detect the loss of oil carried as cargo or as fuel on tank and non-tank vessels greater than 400 gross